ATTACHMENT E

510(k) SUMMARY

JAN 2 8 2010

510(k): K092589

Trade Name: **Thermotex Heat Therapy Systems**

Sponsor:
EAS Consulting Group LLC.
1940 Duke Street, Suite 200
Alexandria, VA 22314
Fax- 703.684.4428

Device Generic Name: **Electric Heating Pad and Infrared Lamp**

Classification:
CFR 890.5740 Class II
CFR 890.5500 Class II

Product Code: IRT, ILY

Product Description:
The Thermotex Heat Therapy Systems provide infrared heat to different areas of the patient's body. The Systems consist of an outer application cover with adjustable pads that enclose the infrared heating elements to treat different areas of the body. The pad's covers are fabricated of nylon-cotton blend. Velcro fasteners on the cover allow for adjusting the cover and pads for optimum contact to the patient's body areas.

Indications for Use:
The Thermotex Heat Therapy Systems are indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

Predicate Devices:
The Thermotex Heat Therapy Systems is substantially equivalent to BIO-MAT 2000 (K072534) – Rich Way International Inc.

Technological Characteristics
The Thermotex Heat Therapy Systems are electrically-powered pads that generate infrared radiation to apply heat to affected body areas. The user can control the pad's heat and temperature to the body by means of a 3-position switch. The manufacturer has evaluated the pad's performance during laboratory bench testing and animal studies to demonstrate infrared radiation capability and its safety.

Substantial Equivalence

The Thermotex Heat Therapy Systems have the same intended use and indications for use as its predicate device. The manufacturer has conducted preclinical bench and animal testing with the Thermotex heat pads. The information from laboratory and animal testing documents that the technological differences between the Thermotex Heat Therapy Systems and the predicate device do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Thermotex Therapy Systems, Ltd.
% EAS Consulting Group LLC
Mr. Eduardo March
1940 Duke Street, Suite 200
Alexandria, Virginia 22314

JAN 2 8 2010

Re: K092589
Trade/Device Name: Thermotex Heat Therapy Systems
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY, IRT
Dated: January 25, 2010
Received: January 26, 2010

Dear Mr. March:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092589

Device Name: THERMOTEX HEAT THERAPY SYSTEMS

Indications for Use:

The Thermotex Heat Therapy Systems are indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

Prescription Use _____ AND / OR Over-the -Counter Use X
(PART 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092589